Conditions of Use Under TSCA Sections 5 and 6

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Mark N. Duvall
Beveridge & Diamond, P.C.

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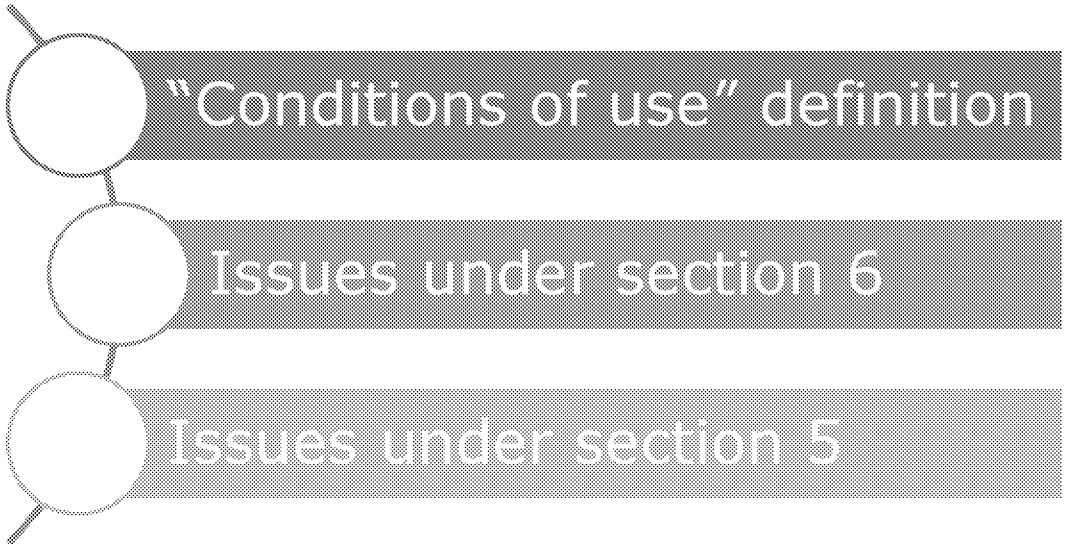
Overview



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"Conditions of use"

- Under TSCA sections 5 and 6, EPA must make decisions about whether a chemical substance "may present"/"is not likely to present"/"presents"/"does not present" –
  - "**an unreasonable risk** of injury to health or environment,
  - without consideration of costs or other nonrisk factors,
  - including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator
  - **under the conditions of use**."

"Conditions of use"

- TSCA § 3(4):
  - "The term 'conditions of use' means the circumstances, **as determined by the Administrator**, under which a chemical substance is **intended**, known, or **reasonably foreseen** to be manufactured, processed, distributed in commerce, used, or disposed of."
  - Chemical-specific, not generic
- In making decisions under sections 5 and 6:
  - EPA has discretion to select among conditions of use
  - But some NGOs maintain that EPA must consider all conditions of use

Scope of a risk evaluation

- § 6(b)(4)(D) – Scope
  - "The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish **the scope of the risk evaluation to be conducted, including the** hazards, exposures, **conditions of use**, and the potentially exposed or susceptible subpopulations **the Administrator expects to consider**".
  - Scope determines scope of risk determination, risk management, and preemption

Content of a risk evaluation

- § 6(b)(4)(F)(ii) – a final risk evaluation must:
  - "describe **whether aggregate or sentinel exposures** to a chemical substance under the conditions of use **were considered**, and the basis for that consideration"

Legislative history

- Senator Vitter (June 6, 2016 Cong. Rec.):
  - "The Agency is well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories of uses are deemed negligible or already well controlled."
  - "**The Agency is given the discretion** to determine the conditions of use that the Agency will address in its evaluation of the priority chemical."

EPA discretion – section 6

- Proposed risk evaluation rule (Jan. 19, 2017)
- Proposed 40 C.F.R. § 702.39(c)(1) re scope:
  - "EPA will identify those uses that constitute the conditions of use that will be assessed during the risk evaluation. **Those uses shall be all circumstances** under which the Agency determines that the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

EPA discretion – section 6

- Final risk evaluation rule, July 20, 2017:
  - 40 C.F.R. § 702.41(c)(1): The scope of a risk evaluation will include "the condition(s) of use, **as determined by the Administrator**, that EPA plans to consider in the risk evaluation."
- Preamble – EPA has discretion, e.g.:
  - May exclude impurities – 1,4-dioxane
  - May exclude legacy uses and related disposal – asbestos
  - But EPA will always include "an evaluation of the conditions of use that raise greatest potential for risk."

EPA needs discretion

- Preamble:
  - "EPA's overall objective of this rule is to ensure that it is able to focus on conducting a **timely, relevant, high-quality, and scientifically credible** evaluation of a chemical substance as a whole …. EPA wants also to ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, **within the statutory deadlines**."

NGO challenges

- Consolidated NGO petitions for review of risk evaluation rule & prioritization rule (9th Cir.)
  - NRDC, Earthjustice, EWG, Sierra Club
  - ACC and other trade associations have intervened
- Expected main issue for risk evaluation challenge: scope of risk evaluations
  - Briefing to be completed by June 2018

PMNs and conditions of use

- Similar issue – in deciding whether a PMN substance "may present"/"is not likely to present" an unreasonable risk, which conditions of use must EPA consider?
  - Those described in the PMN
  - "Reasonably foreseen" uses from PMN
  - "Reasonably foreseen" uses of future manufacturers and processors of the PMN substance once added to the Inventory?
- Affects section 5(e) orders, SNURs

Conditions of use in a PMN

- Risk is a function of hazard and exposure
- If EPA makes a "may present" finding:
  - Remedy – section 5(e) order to restrict exposure
  - Mandatory for PMN submitter
- Possible SNUR for future manufacturers and processors

"Not likely to present"?

- EPA has mostly made that finding solely on basis of low hazard (regardless of conditions of use)
- EPA should also make that finding based on hazard + low exposure concern (taking PMN's conditions of use into account)
  - Where PMN does not raise exposure concerns (e.g., release to water, respirator)
  - Where PMN raises exposure concerns, but is amended to address them

"Reasonably foreseen" uses from PMN's conditions of use

- NGOs: It is "reasonably foreseen" that PMN submitter will not follow PMN's exposure controls after NOC, creating need for "may present" determination
  - Is a PMN (or an amended PMN) binding?
    - NGOs and EPA: no
    - Certification statement
    - "Binding option"?
- Section 5(e) order would clearly be binding
  - But not "necessary to protect against an unreasonable risk"

Future manufacturers and processors after NOC filed

- Is the PMN substance "likely to present" solely because of potential conditions of use of future manufacturers and processors?
- Remedy: section 5(e) order
  - The order would affect only the PMN submitter
  - Future manufacturers and processors would not be parties to the order
- SNUR factors:
  - EPA must consider "reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance"

EPA's planned non-order SNUR

- "Not likely to present" for PMN submitter
  - But not issued until SNUR becomes effective
- NGOs object
  - Section 5(e) order is "required"
  - SNURs not effective or not issued
- PMN submitters object
  - Review completed, but no finding issued
  - Additional months of delay beyond that needed for section 5(e) order

Better non-order SNUR

- EPA should issue "not likely to present" upon completion of review of PMN (or amended PMN)
  - Binding option?
  - PMN submitter can file NOC
- Issue SNUR expeditiously to address conditions of use of possible future manufacturers and processors (and PMN submitter)
  - Virtually no problems in > 30 years of PMN submitter or other manufacturers or processors making intended new use "ongoing" after NOC

NGO challenge

- NRDC petition for review of PMN "framework document"
- ACC, NAM, Safer Chemicals-Healthy Families have intervened
- No briefing schedule yet

Questions?

Mark N. Duvall
Beveridge & Diamond, P.C.
mduvall@bdlaw.com
(202) 789-6090

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